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EXAMINER
RAMIREZ, DELIA M

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 12/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/762,258	GOUT ET AL.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) *5-15,17-31,41-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,16,32-36,38-40* is/are rejected.

7)☒ Claim(s) *37* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 May 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

Claims 1-55 are pending.

Applicant's election with traverse of Group I, claims 1-4, 16, 32-36 drawn to the polynucleotide of SEQ ID NO: 1, vectors and host cells comprising said polynucleotide, amendment of claims 29 and 35, as well as addition of claims 37-55, in Paper No. 8, filed on 10/28/2002 is acknowledged.

Applicant's traverse is on the ground(s) that Group I and XIII share the same the same or corresponding technical features, namely the nucleic acid molecules comprising the human $p70\beta^{s6k}$ gene. Furthermore, Applicants argue that 37 CFR 1.475(b)(2) states that a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to certain combinations of categories, one being a product and process of use of said product.

Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection. In regard to the technical feature linking Groups I and XIII, while one could argue that the technical feature linking Groups I and XIII would have been a polynucleotide encoding a p70 S6 kinase <u>if all the claims as originally presented were drawn to the inventions of Groups I and XIII</u>, it is noted that for unity of invention analysis, all the groups (I-XIV) were considered and not just Groups I and XIII. Therefore, as indicated previously, the technical feature linking all the groups (I-XIV) is the p70 S6 kinase and not the polynucleotide encoding said kinase. Furthermore, as indicated in previous Office Action Paper No. 6, since the technical feature linking Groups I-XIV does not define a contribution over the prior art (see the

teachings of Grove et al. already discussed), the claimed inventions do not meet the requirement of unity of invention under PCT Rule 13.2. Even if one assumes the technical feature to be a polynucleotide encoding a p70 S6 kinase, the claimed inventions still do not meet the requirement of unity of invention under PCT Rule 13.2 since Grove et al. also teaches two human polynucleotides which encode p70 S6 kinases. In regard to 37 CFR 1.475(b)(2), the claims as originally filed lack unity of invention since the claims were not drawn to just one product and a process of use of said product but rather to a variety of products and methods as indicated in previous Office Action Paper No. 6, mailed on 8/26/2002.

The requirement is deemed proper and therefore is made FINAL.

It is noted that while newly added claims 37-40 are directed to the elected invention, newly added claims 41-55 are drawn to a non-elected invention, namely the method of Group XIII. Claims 5-15, 17-31 and 41-55 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

1. The use of the trademarks has been noted throughout this application. See, for example, "Eastman Kodak", "New England Biolabs", "Clontech", etc. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Priority

2. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 119(e) to provisional application No. 60/095268 filed on 8/4/1998.

Information Disclosure Statement

3. Acknowledgement is made of the information disclosure statement (IDS) submitted on 9/5/2001. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

4. The drawings have been reviewed and are approved by a draftsperson under 37 CFR 1.84 or 1.152.

Claim Objections

5. Claim 16 is objected to because of the recitation of "any of claims 1-3". It is suggested that the term be amended to recite "any one of claims 1-3". Appropriate correction is required.

6. Claim 37 is objected to because of the following informalities: the term "vestor" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 3-4, 16, 32-36, 38-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 1 and 3 (claim 16 dependent thereon) are indefinite in the recitation of "molecule which encodes a $p70\beta^{s6k}$ as it is unclear what a $p70\beta^{s6k}$ is. While the specification has defined the polypeptide of SEQ ID NO: 2 as a $p70\beta^{s6k}$, the specification (page 10, lines 10-11) also define a $p70\beta^{s6k}$ protein as an isoform of the newly identified S6 kinase. Since the characteristics of an isoform of $p70\beta^{s6k}$ have not been clearly defined, one cannot clearly establish what is encompassed by the claims. For examination purposes, the term will be interpreted as "encodes any S6 kinase". Correction is required.

10. Claims 1 and 3 (claim 16 dependent thereon) are indefinite in the recitation of "hybridizes to a nucleic acid molecule...under stringent conditions" absent a statement of the conditions under which the hybridization reaction is performed. Nucleic acids which will hybridize under some hybridization conditions will not necessarily hybridize under different conditions. It is suggested that the experimental hybridization/wash conditions be recited in the claim. For examination purposes, the term will be interpreted as "hybridizes to a nucleic acid under any conditions". Correction is required.

11. Claim 4 is indefinite in the recitation of "protein with at least 75% identity to SEQ ID NO: 2" since as written, one cannot clearly establish if the term "75% identity" refers to sequence, length, etc. It is suggested that if the intended meaning of the term is 75% sequence

identity, the term "sequence" be inserted. For examination purposes, it will be assumed that the term relates to sequence identity. Correction is required.

12. Claim 32 (claims 33-34 dependent thereon) is indefinite in the recitation of "a vector comprising the isolated nucleic acid ...., operably linked to a promotor or transcription" for the following reasons. First, as written, it is unclear if the term "operably linked" refers to the isolated nucleic acid or the vector. It is suggested that if the term refers to the isolated nucleic acid, the claim be amended by inserting the term "wherein said nucleic acid is operably....". Second, the term "promotor" appears to be misspelled. In addition, it is unclear what the meaning of the term "transcription" is within the context of the claim. For examination purposes, the claim will be interpreted as being directed to a vector comprising the nucleic acid of claim 2 wherein the nucleic acid is operably linked to a promoter and no patentable weight will be given to the term "transcription". Correction is required.

13. Claim 33 is indefinite in the recitation of "enhancers or upstream activating sequences" as it is unclear which enhancers or which activating sequences are being referred to. It is suggested that if the enhancers and activating sequences relate to transcription, the claim be amended to include the term "transcriptional". Correction is required.

14. Claims 35-36 and 38-39 (claim 40 dependent thereon) are indefinite in the recitation of "$p70\beta^{s6k}$ protein" since it is unclear what a $p70\beta^{s6k}$ is. While the specification has defined the polypeptide of SEQ ID NO: 2 as a $p70\beta^{s6k}$, the specification (page 10, lines 10-11) also define a $p70\beta^{s6k}$ protein as an isoform of the newly identified S6 kinase. Since the characteristics of an isoform of $p70\beta^{s6k}$ have not been clearly defined, one cannot clearly establish what is

encompassed by the claims. For examination purposes, the term will be interpreted as "any S6 kinase". Correction is required.

15. Claims 36, 38-39 (claim 40 dependent thereon) are indefinite in the recitation of "activated $p70\beta^{s6k}$ " as it is unclear what the meaning of the term "activated" is within the context of the claim and the specification does not define the term. As written, one cannot determine if the term "activated" refers to phosphorylation or an increase in its activity. It is suggested that if the intended meaning of the term "activated" is phosphorylated, the claims be amended to recite "phosphorylated" instead. Correction is required.

16. Claim 39 (claim 40 dependent thereon) is indefinite in the recitation of "substitution at a position corresponding to amino acid residue 401 of SEQ ID NO: 2" as it is unclear absent a statement defining what is a position corresponding to amino acid residue 401 of SEQ ID NO: 2. It is unclear if such position is determined based on the length of the polypeptide or based on how this position relates to function. For examination purposes, the claim will be interpreted as being drawn to a vector comprising a polynucleotide which encodes any protein having S6 kinase activity which results from the substitution of amino acid residues in the polypeptide of SEQ ID NO: 2. Correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

17. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

18. Claims 2-4, 16, 32-36, 38-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 2-4 are directed to genera of polynucleotides of any function (see claim rejections under 35 USC 112 second paragraph for claim interpretation) which (1) encode any protein of any function which results from one or more conservative substitutions in the polypeptide of SEQ ID NO: 2, (2) has at least 65% sequence identity to the polynucleotide of SEQ ID NO: 1, (3) encodes a polypeptide at least 75% sequence identical to the polypeptide of SEQ ID NO: 2, or (4) encode a fragment of the polypeptide of SEQ ID NO: 2. Claim 16 is directed to a host cell comprising some of the genera of polynucleotides described above. Claims 32-36, 38-40 are directed to vectors comprising genera of polynucleotides which (1) encode any protein of any function which results from one or more conservative substitutions in the polypeptide of SEQ ID NO: 2, (2) encode any protein having S6 kinase activity, or (3) encode any protein having s6 kinase activity which results from the substitution of amino acid residues in the polypeptide of SEQ ID NO: 2 (see claim rejections under 35 USC 112 second paragraph for claim interpretation). While the specification discloses the structure and function of the polynucleotide of SEQ ID NO: 1 and the polypeptide of SEQ ID NO: 2, there is no disclosure of the function of other polynucleotides as encompass by the claims. In addition, there is no disclosure of the critical structural elements which are required in a polynucleotide to encode a $p70\beta^{s6k}$ polypeptide or how one can distinguish an isoform of $p70\beta^{s6k}$ from other S6 kinases. There is no

disclosure of which amino acid residues in the polypeptide of SEQ ID NO: 2 can be conservatively substituted and still retain the desired activity.

While one could argue that the polynucleotides of the instant claims are adequately described since one can isolate these polynucleotides by sequence comparison using the DNA/amino acid structures disclosed in the instant application or the prior art, the state of the art teaches that sequence comparison alone should not be used to determine function and that small amino acid changes can drastically change the function of a polypeptide. Bork (Genome Research, 10:398-400, 2000) teaches protein function is context dependent, and both molecular and cellular aspects must be considered (page 398). Van de Loo et al. (Proc. Natl. Acad. Sci. 92:6743-6747, 1995) teaches that polypeptides of approximately 67% homology to a desaturase from *Arabidopsis* where found to be hydroxylases once tested for activity. Seffernick et al. (J. Bacteriol. 183(8):2405-2410, 2001) teaches that two naturally occurring Pseudomonas enzymes having 98% amino acid sequence identity catalyze two different reactions: deamination and dehalogenation, therefore having different function. Broun et al. (Science 282:1315-1317, 1998) teaches that as few as four amino acid substitutions can convert an oleate 12-desaturase into a hydrolase and as few as six amino acid substitutions can transform a hydrolase to a desaturase. The specification only discloses a single species of the claimed genera which is insufficient to put one of ordinary skill in the art in possession of all attributes and features of all species within the genera. Thus, one skilled in the art cannot reasonably conclude that Applicant had possession of the claimed invention at the time the instant application was filed.

19. Claims 1-4, 16, 32-36, 38-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polynucleotide of SEQ ID NO: 1 or the polynucleotide encoding the polypeptide of SEQ ID NO: 2, does not reasonably provide enablement for variants of the polynucleotide of SEQ ID NO: 1 of any function, vectors and host cells comprising said polynucleotides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2nd 1400 (Fed. Cir. 1988) are: 1) quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breath of the claims.

The scope of the claims is not commensurate with the enablement provided by the specification in regard to the infinite number of polynucleotides of unknown function encompassed by the claims. As indicated above, while the specification discloses the structure and function of the polynucleotide of SEQ ID NO: 1 and the polypeptide of SEQ ID NO: 2, there is no disclosure of (1) the function of other polynucleotides as encompassed by the claims, (2) the critical structural elements which are required in a polynucleotide to encode a $p70\beta^{s6k}$ polypeptide, (3) which are the structural elements required in a polynucleotide to encode an isoform of $p70\beta^{s6k}$, (4) how one can distinguish an isoform of $p70\beta^{s6k}$ from other S6 kinases, or (5) which are the amino acid residues that can be substituted in the polypeptide of SEQ ID NO: 2 to render a 65% or 75% sequence homolog which is a functional $p70\beta^{s6k}$.

As discussed previously, the state of the art teaches the unpredictability of isolating polynucleotides/polypeptides of similar function using sequence homology as taught by Bork (Genome Research, 10:398-400, 2000), Broun et al. (Science 282:1315-1317, 1998), Van de Loo et al. (Proc. Natl. Acad. Sci. 92:6743-6747, 1995) and Seffernick et al. (J. Bacteriol. 183(8):2405-2410, 2001). Since the amino acid structure determines function, one of skill in the art would require some knowledge or guidance as to how structure correlates with function in order to isolate the claimed polynucleotides. Therefore, due to the lack of relevant examples, the amount of information provided, the lack of knowledge about the critical structural elements required to maintain the desired function, and the unpredictability of the prior art in regard to function based on homology, one of ordinary skill in the art would have to go through the burden of undue experimentation in order to (1) screen and isolate those polynucleotides having the desired function or (2) determine the function of the polynucleotides as encompassed by the claims. Thus, Applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the invention in a manner reasonably correlated with the scope of the claims.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. Claims 1, 3, 4, 16 35-36, 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Grove et al. (Mol. Cell Biol. 11(11):5541-5550, 1991; cited in the IDS). Grove et al. teaches the cloning and expression of two human p70 S6 kinases, vectors comprising the polynucleotides

encoding the kinases and host cells expressing said kinases (pages 5542-5543, Materials and Methods).

Claims 1 and 3 are partially directed to a polynucleotide which can hybridize to the polynucleotide of SEQ ID NO: 1 under any conditions. Claim 4 is partially directed to a polynucleotide which encode a fragment of SEQ ID NO: 2. Claim 16 is partially directed to a host cell comprising the polynucleotides described above. Claims 35-36 and 38 are directed to vectors comprising a polynucleotide encoding a protein of any function (see claim rejections under 35 USC 112, second paragraph for claim interpretation). The polynucleotide of Grove et al. comprises several fragments of the polynucleotide of SEQ ID NO: 1 and encode several fragments of the polypeptide of SEQ ID NO: 2. See attached alignments. As such the polynucleotide of Grove et al. would hybridize to the polynucleotide of SEQ ID NO: 1. Therefore, the teachings of Grove et al. anticipate the claims as written.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

21. Claims 1, 3, 4, 16 35-36, 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Bandman et al. (US Patent No. 5932445, filed on November 7, 1997, published August 3, 1999). Bandman et al. teaches the cloning and expression of human serine/threonine protein kinases, vectors comprising the polynucleotides encoding the kinases and host cells expressing said kinases (columns 17-20).

Claims 1 and 3 are partially directed to a polynucleotide which can hybridize to the polynucleotide of SEQ ID NO: 1 under any conditions. Claim 4 is partially directed to a polynucleotide which encode a fragment of SEQ ID NO: 2. Claim 16 is partially directed to a host cell comprising the polynucleotides described above. Claims 35-36 and 38 are directed to vectors comprising a polynucleotide encoding a protein of any function (see claim rejections under 35 USC 112, second paragraph for claim interpretation). The polynucleotide of Bandman et al. comprises several fragments of the polynucleotide of SEQ ID NO: 1 and encode several fragments of the polypeptide of SEQ ID NO: 2. See attached alignments. As such the polynucleotide of Bandman et al. would hybridize to the polynucleotide of SEQ ID NO: 1. Therefore, the teachings of Bandman et al. anticipate the claims as written.

Conclusion

22. No claim is in condition for allowance.

23. It is noted that if the references cited by the Examiner are too long, only relevant pages will be enclosed with the instant Action.

24. Applicants are requested to submit a clean copy of the pending claims (including amendments, if any) in future written communications to aid in the examination of this application.

25. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with

the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
December 13, 2002

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1600